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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,396	10/19/2006	Peter John Meikle	TLHR-0008US1	3264

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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,396	MEIKLE ET AL.	
	Examiner	Art Unit	
	GARY W. COUNTS	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-73* is/are pending in the application.

4a) Of the above claim(s) *1-41 and 58-73* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/19/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group V, claims 42-57 in the reply filed on 10/13/09 is acknowledged. The traversal is on the ground(s) that a search for the method of Group V would necessarily include the methods of Groups VI and Group VIII. This is not found persuasive because 1) the inventions lack the same or corresponding special technical features because all of the elements of claim 42 in Group V are shown in the prior art (see below 103 rejections), 2) Groups VI and VIII include limitations and additional method steps which are not recited in claim 42. For example, Group VI requires the steps of adding a pooled population of detection antibodies to the exposed pooled population of target capture microspheres and a step of comparing the identity and quantity of each specific subset of LSD target antigen of interest from the sample obtained from a patient having an unknown LSD clinical status to the identity and quantity of the same specific subset of LSD target antigen of interest from the sample obtained from a patient having a known LSD clinical status and these limitations are not required by claim 42. Also, Group VIII requires a first microsphere conjugated to a capture antibody capable of binding a-iduronidase; a second microsphere conjugated to a second capture antibody capable of binding a-glucosidase; a third microsphere conjugated to a third capture antibody capable of binding saposin C; a fourth microsphere conjugated to a fourth capture antibody capable of binding LAMP-1. Which are not required by Group V nor are these limitations required by Group VI.

While searches would be expected to overlap, there is no reason to expect the searches to be coextensive

The requirement is still deemed proper and is therefore maintained.

Currently, claims 1-73 are pending. Claims 1-41 and 58-73 are withdrawn as being directed to non-elected inventions. Claims 42-57 are under examination.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The body of the specification does not disclose the specific panel or combination of LSD antigens recited in claim 50. Specifically LAMP-1, LAMP-2, saposin C, CD45 leukocyte common antigen, LIMP II, CD63. The noted limitations could not be found in the specification.

4. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 50 & 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 50 is vague and indefinite because it is unclear if Applicant intends the subset of LSD antigens is a panel which requires LAMP-1, LAMP-2, saposin C, CD45 leukocyte common antigen, LIMP II, and CD63 profiled as a group together or if Applicant intends that only one of the antigens or a couple of the antigens are profiled. The claim does not make clear if all are profiled as a group or if a select few from those listed are profiled.

Claim 54 is vague and indefinite in reciting “wherein the quantity of each specific subset of LSD target antigen of interest is proportional another specific subset of LSD target antigen of interest”. It is unclear what Applicant intends or is trying to encompass. Is “another specific subset of LSD antigen of interest” a control or standard to which the quantity of each specific subset of LSD target antigen is compared? Are the subsets different or the same or is Applicant referring to something else?

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 42-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meikle et al (WO 00/55632) in view of Chandler et al (US 6,449,562).

Meikle et al disclose methods of diagnosing and monitoring lysosomal storage disorders. Meikle et al disclose that the methods are suitable for large scale screening of subjects for lysosomal storage disorders. Meikle et al discloses that a combination of biochemical markers such as saposins A, B, C, D, *a*-glucosidase, LAMP-1 and LAMP-2 (LSD antigens) are detected in a patients sample (e.g. p. 4, 10, 12, 13). Meikle et al disclose that the sample can be any organ, tissue, or fluid such as whole blood, urine, plasma, and serum (e.g. p. 7, p. 13). Meikle et al discloses that the markers are determined by immunoassay (e.g. pgs 7-10 and 12-14). Meikle et al disclose the use of capture antibodies specific for the markers. Meikle et al disclose contacting the capture antibodies with sample and then contacting the complexes with labeled antibodies (detection antibodies) specific for the markers (p. 7, 8, 13, 14). Meikle et al discloses that the capture antibodies can be on a solid phase such as a bead (particle) (p. 8). Meikle et al discloses that the lysosomal storage disease can be for example mucopolysaccharidosis type II (p. 2) or Niemann-Pick (A/B) (p. 4).

Meikle et al differ from the instant invention in failing to teach a pooled population of target capture microspheres, the target capture microspheres having distinct subsets and passing the exposed pooled population of microspheres through an examination zone.

Chandler et al disclose multiple diagnostic methods for determining multiple analytes in a sample by flow cytometric analysis and for analyzing and presenting the data in real time (e.g. abstract, col 4, lines 49-60). Chandler et al discloses exposing a pooled population of target capture microspheres to sample, the target capture

microspheres having distinct subsets and each distinct subset having one or more characteristic parameters that distinguishes one target capture microsphere of one subset from those of another target capture subset (e.g. columns 4-8, 20-21, 39-41 and figures 1-42). Chandler et al discloses that the capture moiety on the microspheres can be an antibody (col 41, lines 53-67). Chandler et al disclose that the target capture microspheres can be used to simultaneously detect different analytes by utilizing a mixture of different labeled antibodies (pooled population of detection antibodies) wherein each antibody is specific for a different analyte (e.g. col 41, lines 53-67). Chandler et al disclose that these detection antibodies are added to the pooled population of target capture microspheres. Chandler et al discloses that the detection antibodies are labeled with a fluorescent molecule. Chandler et al discloses passing the pooled population of microspheres through an examination zone and determining the identity and quantity of each analyte of interest (e.g. col 1, line 51 - col 2, line 14; col 5). Chandler et al also disclose the use of a predetermined function table to distinguish the subsets (e.g. col 14-16, figures 7-14). Chandler et al discloses that the capture microspheres in each distinct subset exhibit two or more characteristic fluorescence emission classification parameters. Chandler et al also discloses that the subsets differ in at least one fluorescence emission classification parameter (e.g. col 4-6). Chandler et al discloses that the microspheres of a diameter of about 5 micron mean (col 53, lines 64-66). Chandler et al discloses the use of this method and microsphere subsets allow one to rapidly and simultaneously detect a wide variety of analytes of interest in a single assay step (col 4, lines 48-54).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate pooled microsphere subsets and flow cytometric analysis such as taught by Chandler et al with the method and reagents of Meikle et al because Chandler et al teaches that this allows one to rapidly and simultaneously detect a wide variety of analytes of interest in a single assay step.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY W. COUNTS whose telephone number is (571)272-0817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Gary W. Counts/
Examiner, Art Unit 1641

/Melanie Yu/
Primary Examiner, Art Unit 1641